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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,866	05/16/2005	Kenneth J. Ruchala	013869-9005-01	4683

23409 7590 07/21/2008

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EXAMINER	
KISH, JAMES M	
ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
07/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,866	RUCHALA ET AL.	
	Examiner	Art Unit	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 September 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/6/06, 3/6/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to because the words describing the boxes in Figure 11 are indecipherable. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Abstract

The abstract of the disclosure is objected to because the abstract in an application may not exceed 150 words in length. Correction is required. See MPEP § 608.01(b).

Disclosure

The disclosure is objected to because of the following informalities:

Reference to the PCT/US03/07014 should be made on page 1 of the specification.

Appropriate correction is required.

Claim Objections

Claims 14-26 are objected to because of the following informalities:

Claim 14 states, “obtaining at least on image from the patient at the time of treatment delivery to reposition the dose distribution for the patient, if necessary." It is unclear whether the entire step is "if necessary" or if this only applies to "reposition the dose distribution for the patient."

Claim 14 also states, “adjust patient position to better position patient’s internal anatomy relative to dose distribution,” followed by “optimize repositioning of the patient so that the dose distribution matches planned dose distribution.” It is unclear how these two steps are different from one another.

Claim 14 also states, “iterate as necessary…” It is unclear at to which steps of claim 14 are to be iterated.

Claim 15 is objected to because “for” in line 2 should be – from --.

Claim 15 is objected to because “the planning image dose distribution” lacks antecedent basis at lines 2-3. Also, it is noted that at line 3, “possibly in conjunction with image registration” provides for the optional use of image registration. Therefore, this portion of the claim is not given patentable weight.

Claims 17-26 use the terminology, “can be” and/or “can utilize” and/or “can function.” Therefore, the limitations following these terms are optional limitations and are not given patentable weight. Based on this, these claims fail to further limit the claims from which they depend.

Claim 19 is objected to because -- and -- should be inserted between “objective function" and "weights."

Claim 20 states, "wherein results can be utilized…" There has been no previous mention of “results,” therefore it is unclear as to what these results are or how they can be utilized.

Claim 21 is objected to because it states that “contours can be generated by any available method, including by not limited to, [… a list of methods].” If any method can be used the Examiner requests this list to be removed from the claim language for purposes of clarity.

Claim 22 states, "the optimized possibilities" at line 4. This lacks antecedent basis. Furthermore, it is unclear as to whether the portions of the claim within the parentheses are explicit or only exemplary. If they are the latter, the Examiner requests they be removed from the claim language for purposes of clarity.

Claims 24-25 are objected to because contoured anatomy dose repositioning and multiple margin optimization with daily selection have not been stated as requiring images within claims 14, 24 or 25. Therefore, there is no reason they should be limited to any particular image or image modality. Furthermore, these two processes, that is CADR and MMODS, which are also claimed in claims 23 and 26, are best defined by claims 20 and 22, respectively. However, claims 23-26 do not claim dependence from claims 20 or 22.

Claim 26 is objected because it states "wherein process of plan selection in MMODS, and the process of repositioning in CADR can utilize information including but not limited to…" Therefore, this claim states that these processes can utilize information. Furthermore, "the process of repositioning in CADR" lacks antecedent basis because CADR is not a process defined by the claims from which 26 depends.

Claims 23-26 are objected to for failing to provide a further step for the method.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites the limitation "the fraction image" in line 16 and “the fraction” in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-16 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (US Patent No. 5,117,829). Miller discloses a patient alignment system and method for radiation treatment. The method contains the following steps:

1) Obtaining at least one treatment planning image, see column 9, lines 3-8 and column 10, lines 14-22.

2) Preparing a treatment plan for the patient, see column 11, lines 25-27.

3) Preparing a dose distribution plan, see column 11, lines 31-39

4) Obtaining at least one image from the patient at the time of treatment delivery and comparing the at least one treatment planning image to the at least one image taken of the patient at the time of treatment delivery to modify the treatment plan and dose distribution, as well as adjust patient position to better position patient's internal anatomy relative to dose distribution and optimize repositioning of the patient to match dose distributions, see column 15, lines 50-61.

5) Iterate as necessary, see column 15, lines 61-68.

6) Deliver treatment to the patient, see column 16, lines 23-26.

Regarding claim 15, the dose distribution is calculated indirectly based upon the planning image dose distribution in Miller, as found at column 11, lines 31-39 and column 11, line 55 through column 12, line 24.

Regarding both of claims 16 and 20, see column 15, lines 59-68.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Holmes (US Patent No. 5,647,663). Miller discloses a patient alignment system and method for radiation treatment. However, Miller fails to provide the use of an objective function in determining the precise treatment delivery. Holmes teaches a method of radiation treatment planning. In a first step, the user defines a limited set of discrete intensity values to which each beam will conform. The user provides an objective function of the computed dose which mathematically describes the clinical objectives of the treatment which one is trying to achieve. Through an iterative process, the objective function provides for optimized weightings until the user accepts a plan or the computed dose falls within acceptable limits defined by the user. It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the objective function and weighting approach, as set forth by Holmes, in the method of Miller to evaluate and create a precise treatment plan because this method simple scaling and superposition rapidly performed by current electronic computers (column 3, lines 1-3), thereby decreasing the time needed to create a treatment plan.

Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. in view of Jaffray et al (US Patent App. No. 2003/0007601). Miller discloses a patient alignment system and method for radiation treatment. However, Miller fails to create several treatment plans. Jaffray teaches creating a reference plan, as well as a

plurality of additional plans (the constrained plan set) as a function of various translations and/or rotations of the target volume. The appropriate plan may be selected from the constrained plan set for the particular needs. See paragraphs 132-133. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct several plans, as taught by Jaffray, in the method of Miller in order to quickly compensate for the fact that in each treatment session, systematic and/or random variations in patient setup and in the location of the lesion relative to surrounding anatomy can each change the location and orientation of the lesion at the time of treatment compared to that assumed in the radiation therapy treatment plan (see paragraph 6).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

JMK